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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

KEVIN YOO, Individually and on behalf of all others similarly situated, Plaintiff, v. INTRA-CELLULAR THERAPIES, INC., SHARON MATES, LAWRENCE J. HINELINE, and KIMBERLY E. VANOVER, Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Kevin Yoo ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the defendants' public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Intra-Cellular Therapies, Inc. ("Intra-Cellular" or the "Company"), analysts' reports and advisories about the Company,

and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of Intra-Cellular from August 12, 2014 through April 28, 2017, both dates inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

4. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as Defendants conduct business and a significant portion of the Defendants' actions, and the subsequent damages, took place within this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce,

including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying Certification, purchased Intra-Cellular securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

7. Defendant Intra-Cellular is a biopharmaceutical company that is focused on the discovery and clinical development of innovative, small molecule drugs that address underserved medical needs in neuropsychiatric and neurological disorders by targeting intracellular signaling mechanisms within the central nervous system, or CNS. The Company's lead drug candidate, ITI-007 also known as lumateperone, is supposed to treat schizophrenia, behavioral disturbances in dementia, bipolar disorder and other neuropsychiatric and neurological disorders. The Company is incorporated in Delaware and its principal executive offices are located at 430 East 29th Street, New York, New York 10016. The Company's common stock is traded on NASDAQ under the ticker symbol "ITCI."

8. Defendant Sharon Mates ("Mates") has been the Company's Chief Executive Officer ("CEO"), President, and Chairman of the Board throughout the Class Period.

9. Defendant Lawrence J. Hineline ("Hineline") the Company's Chief Financial Officer ("CFO") throughout the Class Period.

10. Defendant Kimberly E. Vanover ("Vanover") has been the Company's Senior Vice President of Clinical Development throughout the Class Period.

11. Defendants Mates, Hineline, and Vanover are sometimes referred to herein as the "Individual Defendants."

12. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

13. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

14. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

15. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements

16. On August 12, 2014, the Company issued a press release entitled, "Intra-Cellular Therapies Reports Financial Results for Second Quarter Ended June 30, 2014," which discussed the safety of the ITI-007-005 Phase 2 study, stating in relevant part:

> ***In December 2013, the Company announced positive topline results from the Company's randomized, placebo- and active-controlled Phase 2 clinical trial of ITI-007 in patients with acutely exacerbated schizophrenia. This study showed a statistically significant improvement in symptoms associated with schizophrenia at the 60 mg dose on the trial's pre-specified primary endpoint and a favorable safety profile.*** The Company presented additional data from the Phase 2 trial in April 2014 in a poster and a live presentation at the 4th Biennial Schizophrenia International Research Society (SIRS) held in Florence, Italy, as summarized below, and in May 2014 at the 167th Annual Meeting of the American Psychiatric Association (APA) held in New York City.
>
> (Emphasis added).

17. On November 25, 2014, Intra-Cellular issued a press release entitled, "Intra-Cellular Therapies Announces Enrollment of First Patient in Phase 3 Trial of ITI-007 for the Treatment of Schizophrenia" which discussed the beginning of the Phase 3 trial of ITI-007-301 study, stating in relevant part:

> NEW YORK, Nov. 25, 2014 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, announced today that the first patient has been enrolled in the ITI-007-301 Phase 3 trial, a randomized, double-blind, placebo-controlled trial designed to demonstrate the efficacy of ITI-007 for the treatment of schizophrenia. The Company anticipates top-line results from this trial could be available as early as the fourth quarter of 2015.
>
> The Company expects to initiate a second ITI-007 Phase 3 trial in schizophrenia, designated as the ITI-007-302 trial, in the first half of 2015. ***In December 2013, the Company announced positive results from a Phase 2 trial in which ITI-007 exhibited antipsychotic efficacy with a favorable safety profile in patients with schizophrenia.***

> "ITI-007 is a first-in-class antipsychotic investigational new drug with a novel mechanism of action," said Dr. Sharon Mates, Chief Executive Officer and Chairman. ***"Starting the enrollment of patients in our first Phase 3 trial of ITI-007 for the treatment of schizophrenia marks an important milestone for the Company and for patients who eagerly await safe and effective alternatives to currently available treatment options. We believe ITI-007 has the potential to broadly address multiple symptom domains, including positive symptoms, negative symptoms and depressive symptoms without debilitating motor side effects or metabolic syndrome commonly associated with some antipsychotic drugs."***
>
> (Emphasis added).

18. On May 18, 2015, the issued a press release entitled, "Intra-Cellular Therapies Announces Further Analyses of the Phase 2 Clinical Trial of ITI-007 in Schizophrenia at the 168th Annual Meeting of the American Psychiatric Association" which discussed the progress of ITI-007, stating in relevant part:

> ***Safety and Tolerability:***
>
> ITI-007 demonstrated a favorable tolerability profile with little or no weight gain, a favorable effect on metabolic parameters, and a reduced risk for akathisia and hyperprolactinemia.
>
> - ITI-007 had little or no effect on weight gain analyses including placebo-adjusted mean weight gain by clinical site. In contrast, risperidone resulted in weight gain of approximately 2 kg after adjusting for placebo response.
> - In the '005 trial patients received blinded study medication for 28 days and were switched to standard of care (SOC) for a 5-day stabilization period prior to hospital discharge. Insulin, glucose and triglyceride levels remained low during the treatment period for patients randomized to either dose of ITI-007, but increased when patients were switched to SOC. In contrast, glucose, insulin and triglyceride levels were increased during risperidone therapy during the 28-day treatment period.
> - Similarly, prolactin levels were low for patients randomized to either dose of ITI-007, but increased after patients were switched to SOC. In contrast, patients on risperidone experienced a significant increase in prolactin levels during the study period.

- ITI-007 demonstrated a low relative risk of akathisia, with rates of akathisia similar to placebo, in contrast to risperidone which showed a relative risk 3X that of placebo.

Patients treated with conventional or newer second generation antipsychotic drugs (SGAs) for schizophrenia have an increased risk of diabetes and other associated diseases including cardiovascular disease, resulting in a significant burden on our healthcare system. Altered metabolic parameters are known to increase disease risk following certain antipsychotic drug use. Prominent among these metabolic risk factors are elevations in plasma glucose, insulin and triglyceride levels. Existing data suggests that ITI-007 does not impact these metabolic parameters in patients with schizophrenia and may have a substantial potential benefit for this patient population.

"The additional analyses presented at APA continue to demonstrate ITI-007's unique safety profile. We believe the finding that patients' metabolic parameters and prolactin are low while on ITI-007, then worsen after being switched to standard of care antipsychotic therapy, speaks to the beneficial profile of ITI-007," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular Therapies. "We believe these analyses continue to support the unique potential benefits of ITI-007 for patients, their families, and the healthcare system. Existing data provide evidence for the positioning of ITI-007 as a potential single stand-alone therapy for the treatment of multiple symptoms associated with schizophrenia including positive symptoms and negative symptoms and symptoms of impaired social function."

(Emphasis added).

19. On September 1, 2015, the Company issued a press release entitled, "Intra-Cellular Therapies Announces Publication of Positive Phase 2 Schizophrenia Study in the Journal Biological Psychiatry" which discussed the results of the Phase 2, ITI-007-005 study, stating in relevant part:

NEW YORK, Sept. 1, 2015 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced the publication of positive results from its ITI-007 Phase 2 clinical trial (ITI-007-005) in patients with schizophrenia. The article, "ITI-007 for the Treatment of Schizophrenia: A 4-Week Randomized, Double-Blind, Controlled Trial" (Lieberman et al. 2015), was published online on September 1st, 2015 in Biological Psychiatry and is available

at http://www.biologicalpsychiatryjournal.com/article/S0006-3223(15)00694-0/abstract.

In the trial, ITI-007 significantly improved symptoms in patients experiencing an acute exacerbation of schizophrenia at a dose of 60 mg daily, as demonstrated by a statistically significant separation from placebo on the PANSS total score at 4 weeks, the primary endpoint. ***Additionally, ITI-007 was found to be comparable to placebo on measures of safety and tolerability.***

(Emphasis added).

20. On December 9, 2015, the Company issued a press release entitled, "Intra-Cellular Therapies Presents Additional Efficacy and Safety Data From the Positive Phase 3 Clinical Trial of ITI-007 for the Treatment of Schizophrenia and From the Positron Emission Tomography Study" which discussed the progress of the ITI-007-301 Phase 3 study, stating in relevant part:

ITI-007 was well-tolerated and demonstrated a safety profile that did not differ from placebo. This study had a high percentage of patients completing treatment, with time to treatment discontinuation (due to any reason) being statistically significantly better with 60 mg ITI-007 than with placebo. The only treatment-emergent adverse events considered at least possibly related to ITI-007, administered orally once daily in the morning, occurring in greater than 5% of patients and at least twice the rate of placebo were somnolence, sedation, and fatigue, all predominantly mild.

ITI-007's motoric, metabolic, and cardiovascular profile was similar to placebo, and there were no clinically significant changes in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, and lipids.

Second generation antipsychotic drugs (SGAs) for schizophrenia expose patients to increased risk of diabetes and other associated diseases including cardiovascular disease, resulting in a significant burden on our healthcare system. SGAs also have motoric adverse events impacting patient quality of life, often leading to poor medication adherence. The Company believes existing data suggest that ITI-007 does not impact these metabolic, cardiovascular and motoric parameters in patients with schizophrenia.

"The Phase 3 trial demonstrated that ITI-007 is efficacious in the treatment of patients with schizophrenia while possessing a favorable safety and tolerability profile particularly in relation to metabolic, motoric and cardiovascular parameters," said Dr. Sharon Mates, Chairman and CEO of Intra-Cellular

Therapies. "These data are consistent with prior results seen in our Phase 2 study and add further evidence to our belief that ITI-007 may represent an improvement on existing therapies for patients with schizophrenia."

(Emphasis added).

21. On June 30, 2016, Intra-Cellular issued a press release entitled "Intra-Cellular Therapies Reports Completion of Enrollment of ITI-007-302 Phase 3 Clinical Trial for the Treatment of Schizophrenia," announcing the beginning of the Phase 3 ITI-007-302, stating in pertinent part:

> NEW YORK, June 30, 2016 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (Nasdaq:ITCI), a biopharmaceutical company focused on the development of therapeutics for central nervous system (CNS) disorders, today announced completion of enrollment in the second Phase 3 clinical trial (ITI-007-302) of the Company's lead product candidate ITI-007 for the treatment of schizophrenia. The Company anticipates topline data will be available later this year.
>
> "The completion of enrollment in our 302 Phase 3 trial is a major milestone in our mission to advance ITI-007 as a new treatment option for patients suffering from mental illness," said Sharon Mates Ph.D., Chairman and CEO of Intra-Cellular Therapies, Inc. "We believe ITI-007 has the potential to advance the treatment of schizophrenia by providing efficacy with a reduced side effect burden, thereby allowing patients to stay on treatment and benefit from enhanced social functioning."
>
> **About the ITI-007-302 Phase 3 Trial**
>
> The Phase 3 clinical trial, ITI-007-302, is a randomized, double-blind, placebo- and active-controlled clinical trial in patients with an acutely exacerbated episode of schizophrenia. In this trial, 696 patients were randomized to receive one of four treatments: ITI-007 60 mg, ITI-007 20 mg, risperidone 4 mg (active control) or placebo in a 1:1:1:1 ratio. Patients receive study treatment orally once daily in the morning for 6 weeks. Clinical conduct includes an approximate one-week screening period before randomization followed by the 6-week study treatment period. Prior to discharge from the study, patients are switched to a standard-of-care antipsychotic treatment during a five-day inpatient stabilization period. Patients are instructed to return for an outpatient safety follow-up visit approximately two weeks following the last dose of study treatment (study day 54). The study is being conducted in 13 clinical sites throughout the United States.
>
> The primary endpoint for this clinical trial is change from baseline at Day 42 on the Positive and Negative Syndrome Scale (PANSS) total score. The PANSS is a

> well-validated 30-item rating scale that measures the ability of a drug to reduce schizophrenia symptom severity (Kay et al., 1987, Schizophrenia Bulletin 13:261-276). The PANSS measures positive symptoms, such as delusions, suspiciousness, and hallucinations; negative symptoms, such as blunted affect, social and emotional withdrawal, and stereotyped thinking; and general psychopathology, such as anxiety, tension, depression, and active social avoidance. The key secondary endpoint is change from baseline at Day 42 on the Clinical Global Impression scale for Severity of Illness (CGI-S) that provides a clinician's expert assessment of the patient's overall symptom severity. Additional secondary endpoints and other measures, including safety and tolerability, which may highlight differentiating clinical features of ITI-007 are also being assessed. ITI-007 60 mg has demonstrated a statistically significant improvement versus placebo in schizophrenia symptoms and a favorable safety and tolerability profile in two prior late-stage clinical studies.

22. On August 4, 2016, the Company held a conference call to discuss the second quarter of 2016 earnings (the "2Q16 Conference Call"). On the 2Q16 Conference Call, Defendant Vanover discussed the ITI-007-302 study, stating in relevant part:

> To-date, ITI-007 has demonstrated a statistically significant improvement versus placebo in the control of symptoms associated with schizophrenia. ***ITI-007 has also shown a safety and tolerability profile similar to placebo in two late-stage clinical studies.***
>
> These data as well as unique pharmacological findings from our ITI-007 Positron Emission Tomography or PET studies were highlighted at various scientific and medical conferences during the second quarter, including the Schizophrenia International Research Society meeting or SIRS, the American Psychiatric Association or APA, the Society of Biological Psychiatry or SOBP and the American Society of Clinical Psychopharmacology or ASCP.
>
> Taken together, these data have demonstrated that ITI-007 reduced psychosis in patients with schizophrenia at relatively low levels of striatal D2 receptor occupancy, lower than the occupancy range required by most drugs currently approved for the treatment of schizophrenia. ***This substantiates the unique pharmacology of ITI-007 as well as its ability to provide broad efficacy with a favorable safety and tolerability profile.***
>
> In our first Phase 3 study, or 301, and our Phase 2 study 005 in schizophrenia, ITI-007 60 milligrams demonstrated antipsychotic efficacy as measured by change from baseline in the PANSS total score versus placebo at study endpoint. ITI-007 required no dose titration, showed early onset, and sustained efficacy for the four weeks of treatment.

In both trials, ITI-007 was well-tolerated with a safety profile similar to placebo.

(Emphasis added).

23. On September 28, 2016, Intra-Cellular issued a press release entitled "Intra-Cellular Therapies Announces Top-Line Results from the Second Phase 3 Trial of ITI-007 in Patients with Schizophrenia (Study '302)," reporting on results of the ITI-007-302 trial, stating in pertinent part:

> NEW YORK, Sept. 28, 2016 (GLOBE NEWSWIRE) -- Intra-Cellular Therapies, Inc. (NASDAQ:ITCI) today announced top-line results from the second Phase 3 clinical trial (Study '302) of ITI-007, an oral, first-in-class investigational medicine for the treatment of schizophrenia. In this trial, neither dose of ITI-007 separated from placebo on the primary endpoint, change from baseline on the Positive and Negative Syndrome Scale (PANSS) total score, in the pre-defined patient population. The active control, risperidone, did separate from placebo. ***In this trial, ITI-007 was statistically significantly better than risperidone on key safety and tolerability parameters and exhibited a safety profile similar to placebo. This replicates the safety and tolerability findings of a previous study (our Phase 2 Study '005) in which the efficacy of ITI-007 60 mg and risperidone, the active control, were similar.*** We believe ITI-007 did not separate from placebo on the pre-specified primary endpoint in Study '302 in part due to an unusually high placebo response at certain sites which disproportionately affected the trial results and contributed to the efficacy outcome of this study compared to our two previous positive efficacy studies. Drug development in psychiatry faces numerous challenges and approved antipsychotics have had negative results as part of their clinical development programs. We are committed and adequately resourced to continue the development of ITI-007 for the treatment of schizophrenia. ***We believe the ITI-007 late-stage clinical development program, including two large, well-controlled positive studies and supportive evidence from this Study '302, collectively provide evidence of the efficacy and safety of ITI-007 for the treatment of schizophrenia.*** Across all three of our efficacy trials, ITI-007 60 mg improved symptoms of schizophrenia with the same magnitude of change from baseline in the primary endpoint, the PANSS total score. We plan to request a meeting with the U.S. Food and Drug Administration's (FDA) Division of Psychiatry Products to discuss the regulatory path for this first-in-class investigational agent.
>
> "It is not uncommon in the field of psychiatry for studies to be challenged by high placebo response and there has been great variability in the effects observed from one study to the next," said Christoph Corell, M.D., Professor of Psychiatry at Hofstra Northwell School of Medicine. "***Taken together, the ITI-007***

> ***schizophrenia program supports ITI-007 as a unique medication with an unprecedented safety and tolerability profile. Moreover, efficacy has been demonstrated in two large-scale schizophrenia studies to date. In one of these studies, ITI-007 and risperidone, the active control, had similar efficacy. In light of the results to date, I believe that ITI-007 represents a unique investigational medication which has the potential to advance the treatment of patients suffering from schizophrenia."***
>
> ***In this study, consistent with our previous schizophrenia studies, ITI-007 was well-tolerated with a safety profile similar to placebo. There were no clinically significant differences with ITI-007 from placebo in akathisia, extrapyramidal symptoms, prolactin, body weight, glucose, insulin, and lipids.*** As expected, risperidone demonstrated a statistically significant increase in weight gain, glucose, cholesterol, triglycerides and prolactin compared to placebo. These increases have a negative impact on patients. In contrast, ITI-007 was statistically significantly better than risperidone on all of these tolerability parameters. There were no significant increases observed with ITI-007 versus placebo on any of these parameters. There continues to be a need for safer and more tolerable medications for patients with schizophrenia, which are not associated with the motoric and cardio-metabolic side effects of many existing treatments, thereby potentially improving compliance and reducing relapse and hospitalizations. We believe ITI-007 has the potential to address this need.
>
> ***"Based on the strength of the clinical data generated in this program to date, including two positive studies, supportive evidence from Study '302 and a consistent, well-tolerated and placebo-like safety profile across all studies, we continue to believe ITI-007 will be an important treatment for patients suffering from schizophrenia. We remain committed to the development of ITI-007 for the treatment of schizophrenia, bipolar depression, agitation associated with dementia, including Alzheimer's disease and other neuropsychiatric indications," said Dr. Sharon Mates, Chairman and CEO of ITCI.***
>
> (Emphasis added).

24. On November 9, 2016, the Company held a conference call to discuss the third quarter of 2016 earnings (the "3Q16 Conference Call"). On the 3Q16 Conference Call Defendant Mates discussed the safety of ITI-007, stating in relevant part:

> In two studies, the efficacy of ITI-007 60 milligrams was demonstrated showing a statistically significant separation from placebo on the primary endpoint Positive and Negative Syndrome Scale or PANSS total score. ***Across all three studies, ITI-007 was found to be well tolerated with a placebo-like safety profile.***
>
> This is so important for patients who currently suffer from side-effects that lead them to discontinue their medication. Importantly, in two studies where risperidone was used as

an active control, ***ITI-007 was statistically significantly superior to risperidone on several key safety and tolerability parameters such as triglyceride, cholesterol, glucose, prolactin and weight gain.***

* * *

We believe the totality of the data from all studies in our ITI-007 late-stage clinical development program supports the efficacy and safety of ITI-007 for the treatment of schizophrenia representing an advancement for patients. We have requested a meeting with the FDA to discuss the submission of our NDA for the treatment of schizophrenia. We expect to providing update on the status of our discussions with the FDA in the first quarter of 2017.

* * *

[W]e do believe that our package to the FDA is robust and that our studies to-date supports the efficacy and the safety of ITI-007 for the treatment of schizophrenia.

* * *

I think that first of all, we – as you know, ***we do believe that our data is robust and that the three studies that we have done supports the efficacy and the safety of ITI-007 for the treatment of schizophrenia***.

(Emphasis added).

25. On March 1, 2017, the Company held a conference call to discuss the fourth quarter of 2016 earnings (the "4Q16 Conference Call"). On the 4Q16 Conference Call, Defendant Mates discussed the safety of ITI-007-302, stating in relevant part:

Additionally, across all three studies, ***Lumateperone was found to be well tolerated with a safety profile similar to placebo*** and was devoid of the clinical irrelevant adverse event including movement disorders and metabolic disturbances commonly observed with other anti-psychotic and which can often lead to non-adherence treatment, discontinuation and relapse.

Importantly in the two studies where risperidone was included as an act of control Lumateperone demonstrated a highly differentiated safety and tolerability profile versus risperidone, the most frequently prescribed anti-psychotic for the treatment of Schizophrenia.

In our studies Lumateperone was statistically significantly superior to risperidone on several key safety and tolerability parameters such as triglycerides, cholesterol, glucose, prolactin and weight gain.

We have been excited and encouraged by the response from the scientific and medical community when we have presented these data at medical conference. New research published recently in JAMA Psychiatry by [Indiscernible] discusses the inherent risk which patients with Schizophrenia have for developing Type-2 diabetes again emphasizing the need for improved treatment options that avoid the cardio metabolic issues associated with other drugs.

We believe Lumateperone can address this unmet need. We have a meeting scheduled with the FDA in late March to discuss the submission of our NDA for Lumateperone for the treatment of Schizophrenia. We expect to provide an update on the status of our discussions following this meeting.

We also had a positive pre NDA meeting with the FDA regarding the chemistry manufacturing and controls, CMC data package. Additionally, we have signed a long term agreement with a third party manufacturer for the supply of Lumateperone in commercial quantities. ***We believe that the Lumateperone late stage clinical development program which includes two positive large, well controlled studies and supportive data from a third study collectively provide evidence for the efficacy and safety of Lumateperone for the treatment of Schizophrenia.***

(Emphasis added).

26. On the 4Q16 Conference Call, Defendants Mates and Vanover had the following exchange with an analysis:

Robert Hazlett

So, can you comment on the risk benefit side, did you comment on that at all?

Sharon Mates

Well, we have an unprecedented safety profile we believe in human's one or two.

Kimberly Vanover

Right. Sol, we believe we have two positive studies of Lumateperone for the treatment of schizophrenia and Lumateperone has shown to be well tolerated with the safety profile similar to placebo and has shown advantages in the clinical trial over the risperidone which we've previously discussed for our clinical program.

(Emphasis added).

27. The statements referenced in ¶¶ 16-26 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operational and financial results, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) findings related to toxicity observed in animals treated with lumateperone (ITI-007); (2) these findings posed an additional safety concern regarding lumateperone; and (3) as a result, Defendants' statements about the Company's business, operations and prospects were materially false and misleading and/or lacked a reasonable bases at all relevant times.

The Truth Emerges

28. On May 1, 2017, before the market opened, the Company issued a press release entitled, "Intra-Cellular Therapies Provides Corporate Update On Schizophrenia Program" which revealed findings of toxicity in animals treated with lumateperone, stating in relevant part:

> As part of our ongoing dialogue with the U.S. Food and Drug Administration (FDA) regarding our lumateperone (also known as ITI-007) development program in schizophrenia, we requested guidance from the FDA on the acceptability of the two positive well controlled clinical trials we have conducted (Study ITI-007-005 and Study ITI-007-301), with supportive evidence from Study ITI-007-302, as the basis for the submission of a new drug application (NDA) for the treatment of schizophrenia. In connection with this request we provided extensive information and data analyses to the FDA relating to the three studies. The FDA has confirmed that the results of Study ITI-007-302 do not preclude us from submitting an NDA based on the efficacy studies we have conducted to date. We are pleased with this response from the FDA and we believe our schizophrenia clinical development program collectively provides evidence of the efficacy and safety of lumateperone for the treatment of schizophrenia.
>
> ***The FDA has raised questions, however, relating to certain findings observed in nonclinical animal toxicology studies of lumateperone and has requested additional information to confirm that the nonclinical findings are not indicative of a safety risk associated with long term exposure in humans.*** These

> findings only occurred in one of the nonclinical toxicology species and only after high exposure to drug related material. We and our expert consultants believe these findings are not indicative of a safety risk for humans due to species differences in the metabolism of lumateperone. In humans, lumateperone and its metabolites are rapidly eliminated from the body and there is no retention of drug or drug related material. In the animal species in question, a substantial amount of drug related metabolites are retained for an extended period of time and metabolites are formed in this species that are not detected in humans.
>
> As we have previously disclosed, in our clinical trials of lumateperone in schizophrenia up to and including 6 weeks treatment duration in humans, lumateperone has a favorable safety and tolerability profile with the incidence of movement disorders and cardiometabolic adverse events similar to placebo and statistically significantly better on several key safety and tolerability parameters than risperidone, the most frequently prescribed antipsychotic for the treatment of schizophrenia. The FDA has not raised any safety concerns regarding the study of lumateperone in short term treatment trials in humans, including our completed schizophrenia clinical trials and our ongoing Phase 3 clinical trials in bipolar depression and agitation associated with dementia, including Alzheimer's disease. With over 1500 people exposed to date, lumateperone has been well-tolerated with a safety profile similar to placebo.
>
> ***We are preparing responses to the FDA's request for additional information and intend to proceed with our long-term safety study of lumateperone in patients with schizophrenia.*** If the FDA deems our responses regarding the nonclinical findings to be sufficient, we intend to submit an NDA for lumateperone for the treatment of schizophrenia by mid-year 2018 supported by the efficacy studies we have conducted to date. ***If the FDA deems our responses insufficient, they may place our longterm safety study on a clinical hold. The results of the long-term safety study will be required to support an NDA approval for a chronic condition such as schizophrenia.***
>
> (Emphasis added).

29. On this news, shares of Intra-Cellular fell $3.33 per share or over 24% from its previous closing price to close at $10.49 per share on May 1, 2017, damaging investors.

30. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

31. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of Intra-Cellular during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

32. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Intra-Cellular securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

33. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

34. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

35. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;

c. whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;

e. whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;

f. whether the prices of Intra-Cellular securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

g. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

36. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

37. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. Intra-Cellular securities are traded in efficient markets;

d. the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on NASDAQ, and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

g. Plaintiff and members of the Class purchased and/or sold Intra-Cellular securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

38. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

39. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material

information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violation of Section 10(b) of The Exchange Act and Rule 10b-5
Against All Defendants

40. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

41. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

42. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

43. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Intra-Cellular securities during the Class Period.

44. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company

were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

45. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

46. As a result of the foregoing, the market price of Intra-Cellular securities were artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of Intra-Cellular securities during the Class Period in purchasing Intra-Cellular securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

47. Had Plaintiff and the other members of the Class been aware that the market price of Intra-Cellular securities had been artificially and falsely inflated by the Company's and the

Individual Defendants' misleading statements and by the material adverse information which the Company's and the Individual Defendants did not disclose, they would not have purchased Intra-Cellular securities at the artificially inflated prices that they did, or at all.

48. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

49. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of Intra-Cellular securities during the Class Period.

COUNT II

Violation of Section 20(a) of The Exchange Act Against The Individual Defendants

50. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

51. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

52. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

53. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press

releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Intra-Cellular securities.

54. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complaint.

55. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: May 12, 2017

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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